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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/800,198	03/05/2001	Corine Vermet	15966-697 CURA-197)	5015
30623	7590	06/16/2003	EXAMINER	
MINTZ, LEVIN, COHN, FERRIS, GLOVSKY AND POPEO, P.C. ONE FINANCIAL CENTER BOSTON, MA 02111			HAMUD, FOZIA M	
			ART UNIT	PAPER NUMBER
			1647	

DATE MAILED: 06/16/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Offic Action Summary</b>	Application No.	Applicant(s)
	09/800,198	VERMET ET AL.
	Examiner	Art Unit
	Fozia M Hamud	1647

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

#### A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) Responsive to communication(s) filed on 27 March 2003.
- 2a) This action is FINAL.                    2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) Claim(s) 1,38 and 41 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) Claim(s) \_\_\_\_\_ is/are allowed.
- 6) Claim(s) 1, 38, 41 is/are rejected.
- 7) Claim(s) \_\_\_\_\_ is/are objected to.
- 8) Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on \_\_\_\_\_ is/are: a) accepted or b) objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) The proposed drawing correction filed on \_\_\_\_\_ is: a) approved b) disapproved by the Examiner.  
If approved, corrected drawings are required in reply to this Office action.
- 12) The oath or declaration is objected to by the Examiner.

#### Priority under 35 U.S.C. §§ 119 and 120

- 13) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) All b) Some \* c) None of:
1. Certified copies of the priority documents have been received.
  2. Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) The translation of the foreign language provisional application has been received.
- 15) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

#### Attachment(s)

- |   |  |
|---|--|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)  | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____ . |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                            | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)  |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) <u>3_10</u> . | 6) <input type="checkbox"/> Other: _____                                     |

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### **Detailed Office Action**

1. Receipt of Applicants' arguments and amendments filed in Paper No.17 on 27 March 2003 is acknowledged. Claims 2-37, 39-40; 42-55 have been canceled and claim 1 has been amended. Thus claims 1, 38 and 41 are pending and under consideration.

2. The following previous objections and rejections are withdrawn in light of Applicants amendment filed in Paper No.17, 03/27/03:

- (I) The objection to claims 1-4 for reciting non-elected SEQ ID Nos.
- (II) The rejection of claim 1 made under 35 U.S.C § 102(a) as being anticipated by Oohashi et al (1999).

#### ***Information disclosure statement:***

3. Copies of all of the references cited in the Search Report (PTO-1449) submitted by Applicants in Paper Nos: 3 and 10, filed on 09 September 2001 and 26 March 2002, respectively, have been found and considered. Therefore, Applicants do not have to resubmit copies of these references.

#### **Claim Rejections under 35 U.S.C. §101/112:**

4a. Claims 1, 38 and 41 stand rejected under 35 U.S.C. §101 for reasons of record set forth in the office action mailed on 17 September 2002 in Paper NO:15, pages 3-6.

Applicants argue that the claimed protein, (SEQ ID NO:8) is homologous to an olfactory receptor protein and is useful as a marker, or therapy for cancers such as lung and kidney cancers, thereby demonstrating a "real world" use and patentable utility.

Applicants submit an Exhibit A, which includes tables that depict rescaled results of quantitative gene expression analyses performed using SEQ ID NO:8, with primers that

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measure relative expression levels in normal cells and tissues as well as pathological tissue samples. Applicants contend that SEQ ID NO:8 is highly expressed in malignant lung and kidney tissues compared to normal lung and kidney tissues. Thus, Applicants contend that the claimed polypeptide of SEQ ID NO:8 can be used for screens for effective therapeutics which modulate the activity, latency or predisposition to human airway epithelial disorders and for treatment for preventing with conditions associated with dysregulation to this gene. Also Applicants assert that the claimed polypeptide can be used to diagnose lung and renal cancer.

Applicants' arguments have been fully considered, but are not deemed persuasive.

With respect to Applicants' first argument, Applicants do not demonstrate that having homology to olfactory receptor protein assures the claimed polypeptide with an activity, and the specification does not disclose any evidence showing that the claimed polypeptide does have a role lung and kidney cancers.

Firstly the data presented in Exhibit A, (table AL, Panel 2D) was not disclosed in the instant specification, at the time the instant Application was filed. Therefore, this data cannot be used to provide specific and substantial asserted utility or a well established utility for the claimed protein. Secondly, in the event that Applicants provide evidence that the data presented on table AL, panel 2D is not new matter and that they were in possession of said data at time of filing, this data is not applicable to the claimed protein. The data on table AL, panel 2D pertains to gene amplification assay utilizing genomic DNA samples from primary tumors and tumor cell lines which demonstrates

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higher expression of the gene encoding SEQ ID NO:8 in lung and kidney cancer tissues compared to normal controls. Thus, the nucleic acid might be used to detect cancer cells due to increased copy number, thus establishing an asserted utility that is specific, substantial and credible for the DNA. However, the increased copy number of DNA does not provide a readily apparent use for the polypeptide, because there is no information regarding the level of expression, an activity, or a role in cancer for the polypeptide.

The data on table AL, panel 2D shows that gene copy number is increased in certain tumor tissue samples, however, it does not necessarily follow that an increase in gene copy number results in increased gene expression and increased protein expression, such that the polypeptide would be useful diagnostically or as target for cancer drug development. For example, Pennica et al, (1998, PNAS USA 95:14717-14722) discloses that, "An analysis of WISP-1 gene amplification in human colon tumors showed a correlation between DNA amplification and over expression, whereas, over expression of WISP-3 RNA was seen in the absence of DNA amplification. In contrast, WISP-2 DNA was amplified in the colon tumors, but mRNA expression was significantly reduced in the majority of tumors compared with the expression in normal colonic mucosa from the same patient", see page 14722, second paragraph of column 1; pages 14720-14721. Therefore, the protein levels cannot be accurately predicted from the level of the corresponding gene.

Thus, the polypeptide of SEQ ID NO:8 lacks a specific or substantial utility, because there is no indication that the polypeptide is increased in the lung or kidney tumors compared to normal controls.

4b. Claims 1, 38 and 41 stand rejected under 35 U.S.C. 112, first paragraph, for reasons of record set forth in the action mailed on 17 September 2002 in Paper NO:15, pages 6-7.

Specifically, the increased copy number of DNA in lung and kidney tumors, does not provide a readily apparent use for the polypeptide of SEQ ID NO:8, because there is no information regarding the level of expression, an activity, or a role in cancer for the polypeptide.

With respect to claims 38 and 41, while instant specification discloses the polypeptide of SEQ ID NO:8, it does not disclose a pharmaceutical composition comprising the polypeptide of SEQ ID NO:8. For the claims to be enabled, the specification must teach how to use the composition for at least one pharmaceutical use without undue experimentation. Steadman's Medical Dictionary (24th Edition, 1982) defines "drug" as "a therapeutic agent; any substance other than food, used in the prevention, diagnosis, alleviation, treatment or cure of disease in man and animal." Ansel et al. (Pharmaceutical Dosage Forms and Drug Delivery Systems, Seventh Edition), says "A drug is defined as an agent intended for use in the diagnosis, mitigation, treatment, cure or prevention of disease in humans or in other animals. One of the most astounding qualities of drugs is the diversity of their actions and effects on the body." The following are examples of "pharmaceutical uses": administering vitamin

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supplements (preventing disease); using labeled antibodies for in vivo imaging (diagnosing disease); administering a substance to alleviate a symptom of a disease (alleviating or treating disease); and administering an antibiotic (curing bacterial infection). Administering a polypeptide to produce antibodies to protect the individual from contracting a disease, i.e., vaccination, is a pharmaceutical use, however, administering a polypeptide to produce antibodies which are then collected from the animal and used in various ways is not a pharmaceutical use. In the present situation, to enable a pharmaceutical use for polypeptide of SEQ ID NO:8 requires the specification to teach how to use the substance, without undue experimentation, for the prevention, diagnosis, alleviation, treatment or cure of a disease in the animal to which the substance is administered. However, the specification does not provide adequate guidance as to how the polypeptide of SEQ ID NO:8 can be used to treat or diagnose any disorders.

Therefore, one of ordinary skill in the art would not know how to use the polypeptide of SEQ ID NO:8 or a pharmaceutical composition comprising said polypeptide.

### ***Conclusion***

7. No claim is allowed.

**THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

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A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

***Advisory Information***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Fozia M Hamud whose telephone number is (703) 308-8891. The examiner can normally be reached on Monday, Wednesday-Thursday, 6:30 am to 4:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Kunz can be reached on (703) 308-4623. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 308-4227 for regular communications and (703) 308-0294 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

Fozia Hamud  
Patent Examiner  
Art Unit 1647  
June 12, 2003

*Gary L. Kunz*  
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